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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/221,931	12/28/98	TSURUO	T WAKAB37.001A

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EXAMINER

BORIN, M

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

03/31/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/221,931

Applicant(s)

Tsuruo et al

Examiner

M. Borin

Group Art Unit

1631



☒ Responsive to communication(s) filed on Feb 23, 2000

☐ This action is **FINAL**.

☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 11 and 17-20 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 11 and 17-20 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Status of Claims***

1. Amendment filed 2/23/00 is acknowledged. Claims 11, 17-20 are pending.

### ***Information Disclosure Statement***

2. The information disclosure statement filed 2/23/00 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The information disclosure statement contains no reference copies. It has been placed in the application file, but the information referred to therein has not been considered.

3. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 U.S.C. § 102***

4. Claims 11, 17-20 are rejected under 35 U.S.C. 102(a) as clearly anticipated by Naasani et al (Biochem. Biophys. Res. Comm., 249, 391-396, 1998). The Naasani reference is prior art since it is published within one year of the present application (filed 12/28/98) by "another" (e.g., an

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authorship entity different from the inventive entity of the present application). The reference teaches that tea catechins, particularly EGCG, a major tea catechin, inhibit telomerase in solution and in intact cells. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. Applicant can overcome the rejection by “perfecting” foreign priority by providing a certified copy and English translation of the priority document which satisfied the requirement for priority under 35 U.S.C. Section 120.

Response to arguments

In the last communication filed 2/23/00, Applicant submits that the communication contains English translation of the priority document. However, no such translated document was located in the file. Therefore, the rejection is maintained.

5. Claims 1-8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C.103(a) as obvious over Fujiki et al. (Nutrition Reviews, 54(11), S67-S70, 1996) or Liao et al. (Cancer Letters, 96,239-243, 1995) or admitted prior art.

The prior art teaches that green tea is effective as a cancer preventive. More specifically, catechins, taken either as a part of tea or in a purified form, are known to be an active ingredient of tea. See Fujiki or Liao references or specification, p. 2. Under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art. When the prior art method

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is the same as a method described in the specification, it can be assumed the method will inherently perform the claimed process. See MPEP 2112.02. In the instant case, the only method step as instantly claimed is contacting cells (ie via administration) with a composition comprising a catechin. It is Examiner's position that any reference teaching exposure of cells, *in vitro* or *in vivo*, to a composition comprising catechins (e.g., green tea) in its normal and usual operation would necessarily perform the method as claimed. It is the Examiners position that all the elements of Applicant's invention with respect to the specified claims are instantly disclosed or fully envisioned by the teaching of the references cited above.

***Claim Rejections - 35 U.S.C. § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 11, 17-20 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The claims are directed to a method of inhibiting telomerase activity. Although this utility is credible and is supported by experimental evidence, it is not a "specific and substantial utility". Although telomerase activity is elevated in cancer cells there is no direct relationship between inhibition of telomerase and attenuating growth or activity of cancer cells. Since neither the

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specification, nor the prior art ascertain that inhibition of telomerase has a specific utility, the asserted utility in this case is essentially is a method of effecting one of intracellular events, which does not define a "real world" context of use.

***Conclusion.***

7. No claims are allowed

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

9. The Art Unit of your application in the PTO has changed. To aid any papers for this application, all further correspondent should be directed to Art Unit 1631.

March 29, 2000



**MICHAEL BORIN, Ph.D.**  
**PATENT EXAMINER**